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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/783,723	02/20/2004	Reynaldo A. Osorio	KYPH-024/00US 305363-2080	6618
22903	7590	01/24/2008	EXAMINER	
COOLEY GODWARD KRONISH LLP ATTN: PATENT GROUP Suite 1100 777 - 6th Street, NW WASHINGTON, DC 20001			CUMBERLEDGE, JERRY L	
			ART UNIT	PAPER NUMBER
			3733	
			MAIL DATE	DELIVERY MODE
			01/24/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/783,723

Applicant(s)

OSORIO ET AL.

Examiner

Jerry Cumberledge

Art Unit

3733

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6-14 and 21-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6-14 and 21-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All: b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 10/31/2007.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application
- ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

Claims 6-13 and 21-33 are rejected under 35 U.S.C. 101 because they are drawn to non-statutory subject matter. In claim 6, applicant positively recites part of a human, i.e. "a reconstructed vertebral body comprising...a first region of cancellous bone...a second region of cancellous bone...". Thus claims 6-14 and 21-23 include a human within their scope and are non-statutory.

Claims 24-32 are rejected under 35 U.S.C. 101 because they are drawn to non-statutory subject matter. In claim 24, applicant positively recites part of a human, i.e. "a reconstructed vertebral body comprising...a region of cortical bone...a first region of cancellous bone...a second region of cancellous bone...". Thus claims 24-32 include a human within their scope and are non-statutory.

Claim 33 is rejected under 35 U.S.C. 101 because it is drawn to non-statutory subject matter. In claim 33, applicant positively recites part of a human, i.e. "...a region of cortical bone...a first region of cancellous bone...a second region of cancellous bone...". Thus claim 33 includes a human within its scope and is non-statutory.

A claim directed to or including within its scope a human is not considered to be patentable subject matter under 35 U.S.C. 101. The grant of a limited, but exclusive property right in a human being is prohibited by the Constitution. In re Wakefield, 422 F.2d 897, 164 USPQ 636 (CCPA 1970).

Regarding the rejections under 35 U.S.C. 101 it is noted by the Examiner that a reconstructed vertebral body is non-statutory subject matter. Since the reconstructed vertebral body is non-statutory subject matter, the Examiner is not considering the reconstructed vertebral body as part of the Applicant's invention for examination purposes.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 6-13 and 21-33 are rejected under 35 U.S.C. 102(e) as being anticipated by Caldalise (US Pat. 5,681,317).

Caldalise disclose a first region of bone filler material (column 2, lines 53-57)(column 1, lines 63-67), the first region of bone filler material defining a periphery of a second cavity within the first cavity, since the two cements are placed in the concentric openings (Fig. 2, refs. 16 and 15) they will be injected in a concentric manner, with one cement disposed within a cavity formed from the other cement (column 2, lines 60-67)(column 3, lines 1-8); and a second region of bone filler material disposed within the second cavity (column 2, lines 60-67)(column 3, lines 1-8).

Caldarise discloses a first region of bone filler material (column 2, lines 53-57)(column 1, lines 63-67) defining at least a portion of a second cavity (Fig. 2, since a first cement is placed within the outer opening, ref. 16); a second region of bone filler material disposed with the second cavity (Fig. 2, since a second cement is placed within the inner opening, ref. 15). Since the openings 15 and 16 are concentric, the outer cement will form a second cavity in which the inner cement will be extruded into. At least one of the first region of bone filler material or the second region of bone filler material includes bone cement (column 1, lines 63-67). At least one of the first region of bone filler material or the second region of bone filler material includes bone graft material (column 1, lines 56-62, i.e. bioactive particles). The first region of bone filler material includes a bone cement that has been hardened for a time period; and the second region of bone filler material includes a bone cement that has been hardened for a time period less than the time period for the first region of bone filler material (column 1, lines 56-67), since the bone cements are capable of being hardened for different time periods prior to injection. The first region of bone filler material and the second region of bone filler material collectively entirely fill the first cavity; and the second region of bone filler material entirely fills the second cavity (column 3, lines 15-20).

Caldarise disclose a first region of bone filler material (Fig. 2, region formed by placing and extruding cement in opening of ref. 16)(column 2, lines 53-57) defining an extravazation-inhibiting barrier (Fig. 2, barrier formed between cement extruded from ref. 16 and ref. 15); and a second region of bone filler material (Fig. 2, region of cement formed by placing and extruding cement in opening of ref. 15). The extravazation-

inhibiting barrier of the first region of bone filler material is disposed between a remaining portion of the first region of bone filler material and the second region of bone filler material (Fig. 2, barrier formed between cement extruded from ref. 16 and ref. 15). The extravazation-inhibiting barrier of the first region of bone filler material defines a second cavity, the second region of bone filler material being disposed within the second cavity (Fig. 2). The extravazation-inhibiting barrier of the first region of bone filler material is configured to inhibit extravazation of the second region of bone filler material (Fig. 2). The first region of bone filler material is mutually exclusive from the second region of bone filler material (Fig. 2). The first region of bone filler material includes a bone cement that has been hardened for a time period; and the second region of bone filler material includes a bone cement that has been hardened for a time period less than the time period for the first region of bone filler material (column 1, lines 56-67), since the bone cements are capable of being hardened for different time periods prior to injection. The first region of bone filler material is a compressed bone cement; and the second region of bone filler material is an uncompressed bone cement (Fig. 2). The first region of bone filler material and the second region of bone filler material collectively fill the first cavity; and the second region of bone filler material collectively fill the second cavity (column 3, lines 15-20).

Caldarise disclose an article of manufacture comprising a first region of bone filler material (Fig. 2, region formed by placing and extruding cement in opening of ref. 16)(column 2, lines 53-57), the first region of bone filler material defining at least a portion of a second cavity (Fig. 2, since a first cement is placed within the outer

opening, ref. 16); a second region of bone filler material disposed within the second cavity (column 2, lines 60-67)(column 3, lines 1-8).

With regard to statements of intended use and other functional statements (e.g. ...bone cement that has been hardened for a time...), they do not impose any structural limitations on the claims distinguishable over the apparatus of Caldarise, which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Caldarise (US Pat. 5,681,317) in view of Shastri et al. (US Pat. 5,837,752).

Caldarise discloses the claimed invention except for at least one of the first region of bone filler material or the second region of bone filler material includes a stent.

Shastri et al. disclose bone cement compositions (column 9, lines 10-19) that can be formed into a shape (e.g. a stent) (column 9, lines 21-27), in order to form a solid article for implantation in order to replace or repair a damaged bone (column 9, lines 14-18).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have constructed at least one of the bone cements of Caldarise as a stent of Shastri et al., in order to form a solid article for implantation in order to replace or repair a damaged bone (column 9, lines 14-18).

Response to Arguments

Applicant's arguments filed 10/31/2007 have been fully considered but they are not persuasive.

With regard to Applicant's arguments directed to the rejections under 35 USC § 101, the examiner notes that patents are not granted for all new and useful inventions and discoveries. The subject matter of the invention or discovery must come within the boundaries set forth by 35 U.S.C. 101, which permits patents to be granted only for "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof." A thing occurring in nature, which is substantially unaltered, is not a "manufacture." A shrimp with the head and digestive tract removed is an example. *Ex parte Grayson*, 51 USPQ 413 (Bd. App. 1941). Here, the vertebral

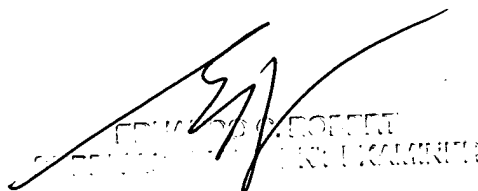
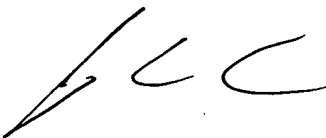
body, or bone, is substantially unaltered and therefore is not a manufacture and as such does not fall within the boundaries of 35 U.S.C. 101.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Cumberledge whose telephone number is (571) 272-2289. The examiner can normally be reached on Monday - Friday, 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



EDUARDO ROBERT
SUPERVISOR